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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,570	01/23/2004	Pamela M. Drake	340082.401	4880

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/763,570	Applicant(s) DRAKE ET AL.	
	Examiner Lora E. Barnhart	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/16/06 has been entered.

Applicant should note that the species election made 7/27/05 still applies to the instant claims. Therefore, the nutrient in claim 1 is limited to the elected species, *i.e.* fructooligosaccharides.

Response to Amendments

Applicant's amendments filed 6/16/06 to claims 1, 5, and 7 have been entered. Claims 4, 11, and 27 have been cancelled in this reply. Claims 1, 2, 5, 7, and 8 remain pending in the current application, of which claims 1, 2, 5, and 7 are being considered on the merits. Prior art references not included with this Office action can be found in a prior action.

Claim Objections

The objection to claim 7 is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 112

The rejections under 35 U.S.C. § 112, second paragraph, are withdrawn in light of the claim amendments.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

M.P.E.P. § 2173.05(u) recites, "It is important to recognize that a trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus a trademark or trade name does not identify or describe the goods associated with the trademark or trade name." If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. § 112, second paragraph. *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). Clarification is required. The examiner queries whether "nystatin" is actually a trademark.

Claim Rejections - 35 USC § 102

The rejection of claim 1 under 35 U.S.C. 102(b) as being anticipated by Gatto et al. (1998, *Journal of Biological Chemistry* 273: 10578-10585) is withdrawn in light of the claim amendments.

Claim Rejections - 35 USC § 103

Claims 1, 2, 5, and 7 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Farmer (2003, U.S. Patent 6,645,506) taken in view of Jaffe (1974, U.S. Patent 3,852,454; reference A). The claims are drawn to a composition comprising isolated or purified bacteria, fructooligosaccharides (FOS), an antimicrobial agent, and

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ascorbic acid. In some dependent claims, the antimicrobial agent is antifungal, in particular nystatin. In some dependent claims, the bacteria are a specific mixture of six bacterial species and are prepared via filtration from their culture media.

Farmer teaches therapeutic compositions comprising *Bacillus coagulans* and fructooligosaccharide (column 25, line 57, through column 26, line 25; "Formulation 1"). Farmer teaches that said composition may also comprise one or more of numerous probiotic bacteria (column 21, line 63, through column 22, line 27). Farmer teaches that the composition may further comprise an antimicrobial agent, for example an anti-fungal compound such as nystatin (column 22, lines 28-51, especially line 45) and an antioxidant (column 17, lines 33-35).

Farmer does not explicitly teach a composition comprising ascorbate or ascorbic acid.

Jaffe teaches that ascorbic acid was a well-known antioxidant at the time of the invention of Farmer.

A person of ordinary skill in the art would have had a reasonable expectation of success in including ascorbic acid in the composition of Farmer because Farmer suggests adding "known antioxidants," and Jaffe teaches that ascorbic acid was a known antioxidant at the time of the invention of Farmer. The skilled artisan would have been motivated to add ascorbic acid to the composition of Farmer because Farmer suggests including antioxidants to facilitate the growth and germination of the bacteria within the composition (column 17, lines 21-42).

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A person of ordinary skill in the art would have had a reasonable expectation of success in including nystatin in the composition of Farmer because Farmer specifically contemplates such an addition; at column 21, lines 55-62, Farmer suggests a composition comprising probiotic bacteria and an anti-fungal compound. The skilled artisan would have been motivated to include nystatin in the composition of Farmer for the expected benefit that fungal infections might be prevented by the administration of said composition.

The selection of probiotic bacteria to be included in the composition of Farmer clearly would have been a routine matter of optimization on the part of the artisan of ordinary skill, said artisan recognizing that Farmer teaches that the bacteria may be one or more of any of numerous probiotic bacteria and that the recited bacteria are art-accepted equivalents (column 2, lines 21-32). A holding of obviousness over the cited claims is therefore clearly required. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

While Farmer does not explicitly teach a composition comprising a mixture of probiotic bacteria, the inclusion of multiple different strains (as required in instant claim 7) does not render the instant composition patentable. Farmer specifically contemplates compositions comprising multiple strains (column 2, lines 19-22). In addition, it is well established that duplicating components with similar functions within a composition is obvious; see *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960) and M.P.E.P. § 2144.04.

It would therefore have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute one or more of the bacteria at columns 21-22 into the exemplified composition of Farmer because Farmer teaches that the bacteria are art-accepted substitutes for each other. It would have been further obvious for the artisan to add nystatin to the composition of Farmer because Farmer teaches that the inclusion of antifungals in bacterial compositions retards the growth of yeast and molds (column 5, line 62, through column 6, line 12). It would have been further obvious for the artisan to add ascorbic acid to the composition of Farmer because Farmer teaches that the inclusion of antioxidants in bacterial compositions facilitate the growth and germination of the bacteria therein (column 17, lines 21-42).

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Applicant's comments have been considered to the extent that they read on the rejection with the newly cited art. Applicants allege that Farmer does not teach or suggest "a kit comprising isolated or purified bacteria, [fructooligosaccharides], an antimicrobial agent, and ascorbic acid" (Reply, page 6, paragraph 1). Applicants allege that there is no basis within the Farmer reference to suggest the instantly claimed combination (Reply, page 6, paragraph 3). These arguments have been fully considered, but they are not persuasive.

Farmer exemplifies a composition at column 25, line 62, through column 26, line 4 ("Formulation 1") that comprises *Bacillus coagulans* and fructooligosaccharides. The motivation to add antimicrobial agents and ascorbic acid to Formulation 1 is provided

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directly by Farmer. Specifically, Farmer teaches compositions comprising live *Bacillus coagulans* that may be used to treat microbial infections; the viability of the *B. coagulans* in the composition of Farmer is, therefore, essential to the composition. Farmer suggests including components that "promot[e] spore germination and/or Bacillus growth... The compositions may also include known anti-microbial, anti-viral, anti-fungal, or anti-yeast agents, all of which must be compatible with maintaining viability of the specific Bacillus active agent, when Bacillus organisms or spores are utilized as the active agent. The various other agents within the therapeutic compositions of the present invention may either be synergists or active agents" (column 17, lines 21-28).

The inclusion of the anti-fungal agent nystatin (specifically suggested for inclusion by Farmer; column 22, line 45) and the antioxidant ascorbic acid (implicitly suggested for inclusion by Farmer; column 17, lines 34-35) facilitate the growth and germination of *Bacillus coagulans* in the compositions of Farmer, and their addition to the composition would have been *prima facie* obvious, since the Farmer reference itself suggests their inclusion and provides motivation for such inclusion, *i.e.*, the protection and cultivation of the *Bacillus* within the compositions.

Patents are relevant as prior art for all they contain. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983). A reference may be relied upon for all that it would have

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reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Nonpreferred embodiments constitute prior art. Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). See M.P.E.P. §2123. In this case, the mere fact that Farmer did not disclose the instantly claimed composition as a preferred embodiment does not render the instantly claimed composition nonobvious.

The rejection of claims 1, 2, and 5 under 35 U.S.C. 103(a) as being unpatentable over van Lengerich et al. (2001, U.S. Patent 6,190,591) is withdrawn in light of the claim amendments and applicant's comments.

No claims are allowed. No claims are free of the art.

Applicant should specifically point out the support for any amendments made to the disclosure in response to this Office action, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP § 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 U.S.C. § 102 or 35 U.S.C. § 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is requested to provide a list of all copending U.S. applications that set forth similar subject matter to the present claims. A copy of such copending claims is requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart

LB


SANDRA E. SAUCIER
PRIMARY EXAMINER